

AMENDMENTS TO THE SPECIFICATION:

Page 1, please replace paragraph [0004] with the following amended paragraph:

[0004] **Description of the Related Art**

Description of the Prior Art

Please replace paragraph [0006] with the following amended paragraph:

[0006] In the case of artificial joint of the cementless type, stable connection of the artificial joint and the bone is achieved by joining with cancellous bone in the proximate portion of the stem, although the cancellous bone takes several months to grow at the earliest.

Page 2, please replace paragraph [0007] with the following amended paragraph:

[0007] When an artificial joint of the cementless type is applied to the hip joint, for example, a stem which is made thicker not only in the proximate portion but also in the distal portion has been used for femoral bone, in order to increase the occupancy ratio of the artificial joint stem in the bone canal of the femoral bone stem. Since the bone canal has anatomical curve, however, the distal end of the artificial hip joint stem comes into contact with the bone inside the bone canal to cause concentration of stress at the contact point, resulting in osteolysis which leads to loosening of the artificial joint, pain and/or bone fracture.

Page 3, please replace paragraph [0010] with the following amended paragraph:

[0010] With such a background as described above, ~~it requires expedient to implant an artificial hip joint of cementless type, and~~ tapered stems and straight stems without distal tips are generally used in implanting surgical operations at present.

Please replace paragraph [0011] with the following amended paragraph:

[0011] Artificial joints of cemented type, on the other hand, ~~is are~~ used in such a way ~~as that~~ the bone canal is filled with cement so as to fix the stem inserted therein and the bone.

Please replace paragraph [0012] with the following amended paragraph:

[0012] For the artificial joints of cemented type, too, such a stem is provided that has a distal tip, made of a plastic or cement of the same kind as the filler cement, is mounted as a centralizer near the distal end of the stem. ~~Major A major~~ role of the distal tip in the artificial joints of cemented type is to position the distal end of the stem at the center of the bone canal, thereby to evenly distribute the filler cement around it. In the artificial joints of cemented type, the inserted stem and the cement are integrated into a single block.

Page 5, please add the following new paragraph after paragraph [0018]:

[0018.5] Other features and advantages of the invention will become apparent from the detailed description contained herein below, taken in conjunction with the drawings, in which:

Please replace paragraph [0019] with the following amended paragraph:

[0019] Fig. 1 is a sectional view showing ~~the~~ an artificial joint stem having the distal tip of the present invention mounted thereon inserted in the bone canal of femoral bone.

Please replace paragraph [0023] with the following amended paragraph:

[0023] Fig. 5 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of another embodiment wherein the fitting hole of the distal tip is offset from the center axis thereof.

Please replace paragraph [0024] with the following amended paragraph:

[0024] Fig. 6 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of a further another embodiment wherein the fitting hole of the distal tip is offset from the center axis thereof.

Page 6, please replace paragraph [0025] with the following amended paragraph:

[0025] Fig. 7 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of ~~further~~ still another embodiment wherein the fitting hole of the distal tip is offset from the center axis thereof.

Please delete page 7 in its entirety.

Page 8, please replace paragraph [0030] with the following amended paragraph:

[0030] In order to achieve the object described above, a first feature of the present invention is a distal tip for the positioning of an artificial joint stem; that is mounted near the distal end portion of the stem of the cementless artificial joint thereby to guide the distal end portion of the stem so as not to make direct contact with the inner surface of the bone canal when the stem of the artificial joint is inserted into the bone canal, and make stable positioning of the stem distal end portion when the insertion of stem is completed, wherein the distal tip is made of a biodegradable and absorbable material.

Page 10, please replace paragraph [0040] with the following amended paragraph:

[0040] Since the outer circumference of the distal tip having diameter larger than that of the stem near the distal end thereof is restricted by the inner surface of the bone canal from being displaced, position of the distal end portion of the stem is also regulated. Accordingly, stable positioning of the distal end portion of the stem in the bone canal is achieved by the a distal chip when the insertion of the stem is completed.

Page 11, please replace paragraph [0043] with the following amended paragraph:

[0043] According to the third feature, in addition to the effects of the second feature, it is made possible to make stable positioning of the distal end portion of the stem at

a position which is offset from the center of the bone canal, by making the mounting means of the distal tip in the form of a fitting hole, fitting projection or screw that is provided on the distal tip, and providing the mounting means at a position offset from the center axis of the distal tip. That is, since human bones are curved to degrees different from one individual to the other, there may be such a case that it is preferable to dispose the distal end portion of the stem in the bone canal at a position which is somewhat offset from the center rather than at the center of the bone canal, in order to keep the stem at a favorable position where the inserted stem is held in well-balanced posture as a whole in the bone canal. Since such a condition of the bone can be known in advance through X-ray imaging, CT, MRI or the like, stable positioning of the distal end portion of the stem can be achieved at a predetermined position which is offset from the center of the bone canal by determining the preferable direction and amount of offsetting the distal end portion of the stem from the center of the bone canal beforehand, and accordingly fitting the distal tip into the stem while adjusting the azimuthal position of the distal tip in the horizontal plane.

Page 12, please replace paragraph [0045] with the following amended paragraph:

[0045] According to the fifth feature, in addition to the effects of any of the first through the fourth feature, it is made possible to ensure sufficient flow of bone marrow in the bone canal without obstruction, since the outer circumference of the distal tip is formed in polygonal or other uneven shape other than **circle circular**.

Page 13, please replace paragraph [0048] with the following amended paragraph:

[0048] Fig. 1 is a sectional view showing the artificial hip joint stem having the distal tip of the present invention mounted thereon inserted in the bone canal of femoral bone. Fig. 2 (A) through (F) are perspective views showing various embodiments of the distal tip employing fitting hole. Fig. 3 (A) and (B) are perspective views showing embodiments of the distal tip of screw type. Fig. 4 is a plan view showing a distal tip of an embodiment wherein fitting hole of the distal tip is offset from the center axis thereof. Fig. 5 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of another embodiment wherein fitting hole of the distal tip is offset from the center axis thereof. Fig. 6 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of further another embodiment wherein fitting hole of the distal tip is offset from the center axis thereof. Fig. 7 (A) and (B) are plan ~~view~~ and longitudinal sectional ~~view~~ views, respectively, showing a distal tip of further another embodiment wherein fitting hole of the distal tip is offset from the center axis thereof. Fig. 8 is a plan view showing an embodiment wherein a ridge protruding toward the center axis is formed on the inner circumference of the fitting hole of the distal tip. Fig. 9 is a plan view showing an embodiment wherein outer circumferential surface of the distal tip is formed in an uneven shape. Fig. 10 (A) and (B) are plan ~~view~~ and horizontal sectional ~~view~~ views, respectively, showing ~~further~~ another embodiment of the distal tip.

Page 14, please replace paragraph [0049] with the following amended paragraph:

[0049] First, with reference made to Fig. 1, reference numeral 1 denotes a ball head of an artificial hip joint, 2 denotes a stem of the artificial hip joint, 3 denotes a proximal part of femoral bone, 4 denotes a bone canal and 5 denotes a circumferential surface processed to be porous in the proximal portion of the artificial hip joint stem.

Page 15, please replace paragraph [0051] with the following amended paragraph:

[0051] When the artificial joint stem 2 is inserted into the bone canal 4, the distal tip 10 guides the insertion of the stem 2 while preventing the distal end portion 2a of the stem 2 from making direct contact with the inner surface of the bone canal of the femoral bone 3 thereby causing a damage, and from obstructing smooth insertion of the stem 2.

Please replace paragraph [0052] with the following amended paragraph:

[0052] **Diameter** The diameter of horizontal section of the distal tip 10 is made larger than the diameter of horizontal section of the portion near the distal end of the stem 2.

Please replace paragraph [0053] with the following amended paragraph:

[0053] When insertion of the artificial joint stem 2 into the bone canal 4 is completed, the outer circumferential surface of the distal tip 10 faces the inner circumferential surface of the bone canal of the femoral bone 3, so that

displacement of the distal tip 10 is constrained within a small region, thereby achieving stable positioning of the distal end portion 2a of the stem 2, too.

Please replace paragraph [0055] with the following amended paragraph:

[0055] The distal tip 10 is made of a biodegradable and absorbable material. For the material decomposed and absorbed in living tissue, PLLA (poly-L-lactic acid), PLA (poly-lactic acid), PGA (poly-glycolic acid), PDS (poly-dioxanone), HA/PLLA (hydroxyapatite/PLLA) copolymer, PLLA/PGA copolymer or lactic acid-caprolactone copolymer may be used individually or two or more of these materials may be used in combination. It ~~needs not to say~~ goes without saying that other biodegradable and absorbable material that ~~is~~ are known or ~~would~~ may be developed in the future may also be used.

Page 16, please replace paragraph [0056] with the following amended paragraph:

[0056] The biodegradable and absorbable material is hydrolyzed and absorbed in the bone canal 4 over time. **Duration** The duration in which the distal tip 10 performs its function can be controlled by adjusting the proportion of the material decomposed and absorbed in living tissue thereby controlling the rate of decomposition and absorption thereof in the living tissue. The duration in which the distal tip 10 performs its function refers to the period during which the cancellous bone grows onto the porous finished surface 5 of the proximate portion of the stem 2 and firmly joins therewith, so that the stem 2 and the femoral bone 3 develop rigid fixation with each other. This period is 3 to 6 months in average while it depends on the individual.

Page 17, please replace paragraph [0060] with the following amended paragraph:

[0060] Configuration of the distal tip 10 may be cylindrical as shown in Fig. 2(D), having a fitting hole 11 that is tapered off being formed along the center axis so as to stop at a mid point thereof without penetrating completely through the tip. The distal tip 10 of this configuration can be mounted on the stem 2 so as to cover the distal end portion 2a of the stem 2 from below.

Please replace paragraph [0061] with the following amended paragraph:

[0061] The distal tip 10 ~~has~~ may have such a configuration as shown in Fig. 2(E), (F) where the top end of the fitting hole 11 of the distal tip 10 has inner diameter near equal to the outer diameter of the top end of the fitting hole 11. This configuration makes it possible to connect the stem 2 and the distal tip 10 with substantially continuous surface without a step at the joint.

Please replace paragraph [0062] with the following amended paragraph:

[0062] Now referring to Fig. 3, the distal tip 10 may be mounted on the stem 2 near the distal end thereof also by means of screw. Fig. 3(A) shows a male screw 12 provided at the top end of the distal tip 10. With a female screw thread not shown in the drawing provided at the distal end portion 2a of the stem 2, the distal tip 10 is mounted by screwing turning the male screw therein. Fig. 3(B) shows a female screw 13 provided at the top end of the distal tip 10. With a male screw not shown in the drawing provided at the distal end portion 2a of stem 2, the distal tip 10 is mounted by screwing both members together.

Page 21, please replace paragraph [0075] with the following amended paragraph:

[0075] In the embodiment shown in Fig. 7, the off-centered fitting hole 11 of the distal tip 10 is formed with a bottom without penetrating therethrough, and a minor fitting hole 15 is provided at the bottom of the fitting hole 11, so that a fitting projection 2c formed on the distal end portion 2a of stem is inserted into the minor fitting hole 15 thereby to mount the distal tip 10 on the stem 2.

Please replace paragraph [0076] with the following amended paragraph:

[0076] The minor fitting hole 15 is provided at a position Q offset from the center axis P of the distal tip 10. Position of the distal end portion 2a of the stem 2 can be adjusted in the bone canal 4 by fitting the minor fitting hole 15 and the fitting projection 2c of the stem 2 ~~while~~ together and turning with respect to each other ~~it~~ in the circumferential direction and to adjusting adjust the position.

Page 22, please replace paragraph [0080] with the following amended paragraph:

[0080] As shown in Fig. 9, the outer circumference of the distal tip 10 may not necessarily be circular. The outer circumference of the distal tip 10 may be formed in polygonal or other uneven shape. In Fig. 9, bulges 17 are provided at equal intervals on the outer circumference of the distal tip 10. By forming the outer circumference of the distal tip 10 in uneven shape, it is made possible to allow bone marrow or the like to flow freely through the clearance among the unevenness.

Please replace paragraph [0081] with the following amended paragraph:

[0081] **Fig.** Fig. 10 shows another embodiment of the distal tip of the present invention. In this embodiment, the distal tip 10 is made in pin shape. A plurality of the pin-shaped distal tips 10 are prepared and are inserted into mounting holes 2d disposed at appropriate intervals (60 degrees in the case of this embodiment) along the circumference of the stem 2 near the distal end 2a thereof for mounting. With the plurality of pin-shaped distal tips 10 mounted in radial configuration on the circumference of the stem 2 near the distal end 2a thereof, the distal end portion 2a of the stem 2 can be positioned in stable condition while being separated from the inner surface of the bone canal 4.

Page 23, please replace paragraph [0083] with the following amended paragraph:

[0083] **Base-side** The mounting end of the pin-shaped distal **tip** tips 10 may also be threaded so as to be mounted by screwing into **the** threaded mounting **hole** holes 2d of the stem 2.

Page 25, please replace paragraph [0089] with the following amended paragraph:

[0089] Moreover, since the stem is provided, at a position near the distal end thereof, with the distal tip having a diameter larger than the diameter of the stem **thereof**, sufficiently stable positioning of the distal end portion of the stem can be achieved in the bone canal when insertion of the stem is completed.

Please replace paragraph [0091] with the following amended paragraph:

[0091] According to the ~~distal tip~~ embodiment for positioning of the artificial joint stem ~~described in claim 3, in addition to the effects of the constitution described in claim 2; wherein the distal tip has a diameter greater than the diameter of the stem near its end and the distal tip is mounted by means of a fitting hole, a fitting protrusion or a screw offset from the center of the distal tip,~~ because of such a constitution as the mounting means for the distal tip is the fitting hole, the fitting projection, the screw or the like that is provided at a position which is offset from the center axis of the distal tip, the mounting means comprising the fitting hole, the fitting projection or the screw can be easily and reliably mounted at a position which is offset from the center axis of the distal tip.

Page 26, please replace paragraph [0094] with the following amended paragraph:

[0094] According to the ~~embodiment of the~~ distal tip ~~for positioning of the artificial joint stem described in claim 4, in addition to the effects of the constitution described in claim 2 or 3, because~~ wherein the mounting means for the distal tip is provided in the form of fitting hole and the fitting hole is provided with the projection or ridge that protrudes from the inner circumferential surface toward the center of the fitting hole, the distal tip can be fitted into the stem more firmly and securely than in a case in which the inner circumferential surface of the fitting hole is a smooth surface. Moreover, the projection or ridge formed in the fitting hole ensures the flow of bone marrow even after the fitting hole has been fitted with the stem.

Please replace paragraph [0095] with the following amended paragraph:

[0095] According to the embodiment of the distal tip for positioning of the artificial joint stem ~~described in claim 5, in addition to the effects of the constitution described in one of claims 1 through 4, since wherein~~ the distal tip is made in such a configuration as the outer circumference has polygonal or other uneven shape other than circle, it is made possible to ensure sufficient flow of bone marrow in the bone canal without obstruction under the condition that the distal end portion of the stem is positioned in the bone canal by means of the distal tip.

Please replace paragraph [0096] with the following amended paragraph:

[0096] According to the embodiment of the distal tip for positioning of the artificial joint stem ~~described in claim 6, in addition to the effects of the constitution described in claim 1, since wherein~~ the distal tips are pin-shaped and are mounted by inserting into a plurality of fitting holes that are provided at appropriate intervals in the circumferential direction of the stem near the distal end of the artificial joint stem, easy and reliable positioning of the distal end portion of the stem in the bone canal can be achieved by using the pin-shaped distal tips. Furthermore, since the distal tips have pin shape, preparation for the implantation can be easily made by inserting the distal tip into the mounting hole of the stem.

Page 27, please replace paragraph [0097] with the following amended paragraph:

[0097] According to the embodiment of the distal tip for positioning of the artificial joint stem ~~described in claim 7, in addition to the effects of the constitution described in claim 6, since wherein~~ the distal tips having different lengths are

prepared so that projecting lengths of the distal tips are different along the circumference when a plurality of distal tips are mounted at appropriate intervals along the circumference of the stem near the distal end thereof, free and reliable positioning of the distal end portion of the stem can be made very easily at an off-centered predetermined position in the bone canal by combining the pin-shaped distal tips of various lengths.

Please add the following new paragraph after paragraph [0097]:

[0098] The foregoing relates to preferred exemplary embodiments of the invention, it being understood that other variants and embodiments thereof are possible within the spirit and scope of the invention, the latter being defined by the appended claims.